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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,164

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Sue Ann Carlidge

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EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,164	<b>Applicant(s)</b> CARTLIDGE, SUE ANN	
	<b>Examiner</b> PHUONG HUYNH	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-53, 61-62 and 63 is/are allowed.
- 6) ☒ Claim(s) 54-60 and 64-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Claims 44-66 are pending.
2. In view of the claims amendment filed June 4, 2008, all previous rejections are hereby withdrawn.
3. Claims 44-49, 52 and 53 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 50-51, and 54-66 directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on July 28, 2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claims 44-66 are being acted upon in this Office Action.
5. The following new grounds of rejections are necessitated by the amendment filed June 4, 2008.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 54-60 and 64-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is new matter.**

The recitation of "a method for detecting the activation of KDR/Flk-1 comprising mixing the antibody generated using a peptide consisting of the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2 as an immunogen with a biological sample and detecting a signal which indicates activation state using NMR to follow changes in the phosphorylation state of Y1214 of KDR/Flk-1" in claim 58 has no support in the specification or the claims as originally filed. This is new matter.

At the time of filing, the specification at page 5, lines 1-9 discloses the use of KDR/Flk-1 epitope Y1214 as a marker in the measurement of a change in the activation state of the KDR/Flk-1 receptor is to measure the phosphorylation state's of KDR/Flk-1 receptor activated in the presence of adenosine triphosphate labeled with radioactive phosphate to determine the level of radioactivity of the KDR/Flk-1 receptor comprising Y1214. The specification discloses measuring the presence or levels of phosphorylated KDR/Flk-1 using said antibody in fluorimetric assays, chromogenic assays, radiolabeled assays or chemilunescence assays, see page 5.

With respect to claim 54, mixing the antibody generated using a peptide consisting of SEQ ID NO: 2 as immunogen (non-phosphorylated peptide) with a biological sample does not lead to indication of *activation* of KDR/Flk-1 because the antibody binds to non-phosphorylated epitope 1214 of KDR/Flk-1.

Further, the specification defines "activation state" is any changes in the *molecular conformation* of KDR/Flk-1 receptor which leads to the direct or indirect modulation of activity of another protein or other proteins within the cell membrane or any other part of a animal or human cell, see page 8, lines 14-17. However, there is no disclosure as how the antibody generated using a peptide consisting of SEQ ID NO: 2 as immunogen (non-phosphorylated peptide) or a peptide consisting of SEQ ID NO: 1 as immunogen (phosphorylated peptide) that binds to the intracellular domain of KDR/Flk-1 receptor, changes the conformation of such receptor.

Takahashi et al (of record) shows Y1214 epitope of KDR/Flk-1 is located intracellular domain of KDR/Flk-1 receptor (see caption of FIG 1A, in particular).

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The claimed antibody must bind to intracellular epitope Y1214 of the KDR/Flk-1 in order to modulate directly or indirectly the conformation of said KDR/Flk-1 receptor. There is no disclosure of any antibody that binds to Y1214 epitope of KDR/Flk-1 lead to conformation changes of such receptor for the claimed method. There is no showing as how the antibody gets inside the cell.

With respect to claims 64-66, the recitation of a method of determining whether a chemical compound is an inhibitor in claim 64 has no support in the specification and the claims as originally filed. This is new matter. It would be helpful if applicant could point out the support for said newly submitted claims 64-66.

Accordingly, one of skill in the art would conclude that applicant was not in possession of the claimed method as set forth in claims 54-60 and 64-66 as a whole at the time of filing. Therefore, the specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claims 54-60 and 64-66.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115). Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001 and revision of the Written Description Training materials, posed April 11, 2008 <http://www.USPTO.gov/web/menu/written.pdf>.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is incomplete for failing to achieve the goal set forth in the preamble. There is no nexus between phosphorylation of KDR/Flk-1 and the chemical compound is an inhibitor of KDR/Flk-1.

10. Claims 44-53, 61-62 and 63 are allowed.

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.
13. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Primary Examiner, Art Unit 1644

August 29, 2008